

General

Guideline Title

Telaprevir for the treatment of genotype 1 chronic hepatitis C.

Bibliographic Source(s)

National Institute for Health and Clinical Excellence (NICE). Telaprevir for the treatment of genotype 1 chronic hepatitis C. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Apr. 47 p. (Technology appraisal guidance; no. 252).

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Telaprevir in combination with peginterferon alfa and ribavirin is recommended as an option for the treatment of genotype 1 chronic hepatitis C in adults with compensated liver disease:

- Who are previously untreated or
- In whom previous treatment with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin has failed, including people whose condition has relapsed, has partially responded or did not respond

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Genotype 1 chronic hepatitis C

Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

Clinical Specialty

Family Practice

Gastroenterology

Infectious Diseases

Internal Medicine

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To assess the clinical effectiveness and cost-effectiveness of telaprevir for the treatment of genotype 1 chronic hepatitis C

Target Population

Treatment-naïve and treatment-experienced adult patients with genotype 1 chronic hepatitis C (CHC)

Interventions and Practices Considered

Telaprevir

Major Outcomes Considered

- Clinical effectiveness
 - Sustained virologic response (SVR)
 - Extended rapid virological response (eRVR)
 - Relapse rates
 - Virologic failure
 - Adherence
 - Discontinuation rates
 - Duration of treatment
 - Health-related quality of life (HRQoL)
 - Fatigue
- Cost-effectiveness

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The Evidence Review Group (ERG) report for this technology appraisal was prepared by the Southampton Health Technology Assessments Centre (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Critique of Manufacturer's Approach to Systematic Review

Description of Manufacturer's Search Strategy

The manufacturer's literature searches were checked by an information scientist. Overall the search strategies were considered to be reasonably comprehensive, fit for purpose and reproducible, having a balance of descriptor and free text terms with correctly linked sets. The databases, hosts, dates and strategies were specified clearly in the manufacturer's submission (MS). The MS records use of the EMBASE host platform, whereas the ERG uses Ovid and therefore would be unable to exactly re-run the searches. However, the ERG anticipates that if the searches were to be re-run, results would be comparable.

Conference proceedings were searched on relevant websites/databases and dates were provided. Conference proceedings were searched from 2003 onwards. Abstracts were included in the searches. There is no overt search documenting the use of in-house company databases, nor recording of a strategy or sources used to identify on-going trials. However, two on-going trials were identified, and there is reference to records from clinicaltrials.gov in the MS text. It appears from the manufacturer's response to clarification questions that a specific search for on-going trials was not conducted but rather 'on-going trials were not excluded from the main clinical effectiveness searches.' The ERG consulted on-going trials databases to identify any additional unpublished data using the following sources: UK Clinical Research Network (UKCRN), controlled trials.com, clinicaltrials.gov and ICTRP (World Health Organisation [WHO] International Clinical Trials Registry Platform). The results were checked by an ERG reviewer. One additional on-going trial relevant to the decision problem was identified.

Statement of the Inclusion/Exclusion Criteria Used in the Study Selection

The MS clearly states the inclusion and exclusion criteria, and these reflect the final scope issued by NICE and the licensed indication. No limits were placed on inclusion relating to the quality of the randomised controlled trials (RCTs) or the setting, but these were not requirements of the final scope. RCTs were limited to English language publications.

The MS presents a flow diagram illustrating the number of studies identified from searches and each stage of the inclusion/exclusion process. Citations identified from conference searches are presented separately in the diagram. Reasons for excluding citations and conference abstracts after first screening are provided in full, but reasons for exclusion of studies and conference abstracts at the full publication review stage are not provided.

Studies were restricted to RCTs. Comparative observational studies would only be included to fill the data gaps in RCT evidence although none were identified by the systematic literature review. The MS states that smaller studies were excluded (n<30) 'as these are typically phase I and dose-ranging studies,' which is not unreasonable. The MS states that restricting the trials to English language publications only would not limit the results substantially due to data availability in the English language and the ERG would agree.

Economic Evaluation

The manufacturer conducted a systematic search of the literature to identify economic evaluations of anti-viral treatment for CHC. Although a thorough cost-effectiveness search is documented for Medline and EMBASE, the MS omitted National Health Service Economic Evaluation Database (NHS EED) and EconLit searches in their original submission. Further to the ERG's clarification questions, the manufacturer ran searches on these databases and reported that no additional references were identified on cross-checking with their prior Medline and EMBASE cost searches. The review did not identify any studies that included telaprevir as a treatment for adults with genotype 1 CHC.

Number of Source Documents

Clinical Effectiveness

• Two randomised controlled trials (RCTs) were included in the review.

Cost-effectiveness

- No published cost-effectiveness analyses were identified.
- The manufacturer submitted an economic model

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The Evidence Review Group (ERG) report for this technology appraisal was prepared by the Southampton Health Technology Assessments Centre (see the "Availability of Companion Documents" field).

Clinical Effectiveness

Description and Critique of the Approach to Validity Assessment

The manufacturer's quality assessment is appropriate and follows the NICE criteria. The published paper for the ADVANCE trial reports no information relating to randomisation, concealment of treatment allocation or blinding but refers to a protocol available online. More methodological information was reported in the published paper for the REALIZE trial, but further details are again given in an online protocol. Both these protocols are extensive, and the ERG therefore had limited time to search for information within them to check against the manufacturer's submission (MS). Table 2 of the ERG report (see the "Availability of Companion Documents" field) shows the assessment of study quality for each randomised controlled trial (RCT) by the manufacturer and the ERG. As the table shows, there are some differences in quality assessment between the MS and ERG. A large proportion of the clinical effectiveness data was sourced from unpublished clinical study reports (CSRs) and it is not clear whether these have undergone quality assessment. After seeking clarification from the manufacturer who stated that 'standard procedures were completed', this remains unclear.

Description and Critique of the Manufacturer's Approach to Trial Statistics

Both trials (ADVANCE and REALIZE) evaluated two telaprevir arms versus placebo/peginterferon alfa and ribavirin (PBO/PR) (control) but omitted reporting one of the telaprevir arms each in the MS due to the use of unlicensed doses or regimens (an approach which is considered

appropriate). For both RCTs, analysis of the primary end point was based on a logistic regression model with treatment group and baseline hepatitis C virus ribonucleic acid (HCV RNA) (both trials), genotype 1 subtype (ADVANCE) and type of prior response (REALIZE) as factors. The ADVANCE trial also conducted a pre-specified subgroup treatment effect analysis related to 10 baseline variables. The REALIZE trial used a Hochberg procedure to adjust for multiple comparisons; the method used to adjust for multiple comparisons in the ADVANCE trial was not stated in the MS or the trial publication. The sample size/power calculation was performed with the use of a two-sided continuity-corrected chisquare test for both trials. Neither the trial publications nor the MS reported on the methods of analysis for secondary outcomes.

Results for all relevant outcomes are presented in the MS, but odds ratios (ORs), absolute differences, 95% confidence intervals (CIs) and p values are not reported for a number of outcomes.

Strict intention-to-treat (ITT) analyses of all patients randomised were not carried out in either study but rather all randomised patients who had received at least one dose of study medication. This population is referred to by the manufacturer as the 'Full Analysis' set. The numbers randomised who subsequently did not receive study drugs was very small and this discrepancy is considered unlikely to have impacted the results.

Description and Critique of the Manufacturer's Approach to the Evidence Synthesis

On the whole, the tabulated data in the MS clinical effectiveness review reflect the data in the published trials with two minor incorrect values. However, as noted, a substantial amount of the data has been taken from the CSRs (rather than the published papers). Another problem with the narrative review is that much of the interpretation is based on comparisons of percentage values without any effect size (ORs or relative risks [RRs]), confidence intervals or statistical significance tests (*p* values).

A meta-analysis of the two included trials was not conducted. The MS states this was because 'ADVANCE provides a comparison in treatment-naïve patients and REALIZE in treatment-experienced patients and the trials provide a direct head-to-head comparison, therefore a meta-analysis is not considered appropriate'. The ERG is in agreement that a meta-analysis would not be appropriate given that the trials are in different patient populations.

An indirect comparison was not necessary as the included trials evaluated a direct head-to-head comparison of the technology with the current standard of care. No mixed treatment comparison (MTC) was conducted.

See Section 3 of the ERG report (see the "Availability of Companion Documents" field) for more information on clinical effectiveness analysis.

Economic Evaluation

Cost-Effectiveness Analysis (CEA) Methods

The cost-effectiveness analysis uses a Markov model to estimate the cost-effectiveness of telaprevir treatment for 12 weeks (T12)/PR compared with PR in adults with genotype 1 CHC. Separate base case analyses are reported for treatment-naïve patients and for those who had previously been treated. The model adopted a lifetime horizon, with an annual cycle length.

Deterministic sensitivity analyses (DSA), scenario analyses, and probabilistic sensitivity analyses (PSA) were performed.

The MS states that the model assumptions and functionality were validated by an independent health economist with expertise in CHC modelling, and by further independent reviews of each model (for treatment-naïve and treatment-experienced populations) although no further details of the review process are provided. The MS does not report whether the models were validated against any external data.

Critical Appraisal of Manufacturer's Submitted Economic Evaluation

The ERG have considered the methods applied in the economic evaluation in the context of the critical appraisal questions listed in Table 6 of the ERG report (see the "Availability of Companion Documents" field), drawn from common checklists for economic evaluation methods (e.g., Drummond and colleagues).

Modelling Approach/Model Structure

The modelling approach and structure adopted by the manufacturer appear reasonable and are based on previous models in this disease area. The structural assumptions are clearly stated. Whilst a lifetime horizon is appropriate in order to reflect the differences in the alternatives, the lifetime horizon of 70 years appears long as the patient starting age in the model is 50 years. This results in patients being alive in the model and potentially accruing quality-adjusted life years (QALYs) theoretically at 120 years old. However, these numbers are a small proportion and do not appear to substantially impact on the overall incremental cost-effectiveness ratio (ICER).

Internal Consistency

The electronic model is coded in Microsoft Excel and is fully executable. Models inputs can be varied by changing values on the relevant input worksheets, and the results of the base case analyses are presented on the 'Results' worksheet.

The MS reported that an independent external methodologist reviewed both assumptions around data inputs and the functionality of the model during model development. It is further reported that two independent reviewers then separately reviewed the treatment-naïve and treatment-experienced models. While the models were stated to have been found to be 'clear, transparent, intuitive and fully functional', there is no further documentation or evidence in the model of internal validation checks, or detailed reporting of what these procedures showed.

External Consistency

The MS does not state that the model has been calibrated against independent data, and does not report further techniques for external validation. It is stated in the 'interpretation of economic evidence' that there are no published economic models exploring the cost-effectiveness of telaprevir. However, there are published models in peginterferon alfa-2a and ribavirin which could have been used for external comparison. The model structure and data inputs including transition probabilities, resource use and costs are substantially based upon, or derived directly from, previously published models in patients with CHC, and therefore there are unlikely to be concerns over external consistency. The economic evaluation was consistent with the NICE reference case.

See Section 4 of the ERG report (see the "Availability of Companion Documents" field) for more information on cost-effectiveness methods.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who Is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

The manufacturer submitted two de novo economic analyses that assessed the cost-effectiveness of telaprevir plus pegylated interferon alfa-2a/ribavirin (PEG2a/R) for the treatment of genotype 1 chronic hepatitis C virus (HCV) in adults, one each for patients who were previously untreated and patients who were previously treated.

The manufacturer developed a Markov model based on other published health economic models of chronic HCV. The model simulates the natural history of chronic hepatitis C infection and extrapolates a patient's lifetime risk of developing advanced liver disease. The potential for decreased adherence in routine clinical practice compared with the trial setting.

For the previously untreated population, the manufacturer's model estimated that telaprevir plus PEG2a/R provides an incremental health gain of 0.84 quality-adjusted life years (QALYs) compared with PEG2a/R alone, at an incremental cost of £11,430, resulting in an incremental cost-effectiveness ratio (ICER) of £13,553 per QALY gained. For the previously treated population, the manufacturer's model estimated that telaprevir plus PEG2a/R provides an incremental health gain of 1.17 QALYs compared with PEG2a/R alone, at an incremental cost of £10,195, resulting in an ICER of £8688 per QALY gained.

The Evidence Review Group (ERG) conducted additional exploratory analyses to address some of the issues identified in the manufacturer's economic model. The ERG varied the mean age and distribution of disease severity at treatment to bring them in line with previous National Institute for Health and Clinical Excellence (NICE) appraisals of antiviral therapy for chronic hepatitis C. The proportion of patients with cirrhosis modelled by the ERG was lower than in the manufacturer's base case (10% compared with 20% for previously untreated patients and 32% compared with 48% for previously treated patients). The mean ages were approximately 5 years lower in the ERG's analyses than in the manufacturer's base case. These changes reduced the ICER from £13,553 to £11,916 per QALY gained for previously untreated patients and from £8688 to £8086 per QALY gained for previously treated patients.

Summary of Appraisal Committee's Key Conclusions

The Committee noted a number of health-related benefits, which, if taken into account, would decrease the ICERs:

- The model did not account for the benefit to public health from reducing transmission of HCV as a result of successful treatment.
- Achieving a sustained viral response would reduce the stigma associated with having HCV.

The Committee also noted a number of factors, which, if taken into account, would increase the ICERs:

- The increased mortality rate of patients with compensated cirrhosis
- The occasional use of erythropoietin in patients with severe anaemia
- The use of peginterferon alfa-2b instead of peginterferon alfa-2a
- The issue of re-infection
- The potential for decreased adherence in routine clinical practice compared with the trial setting

On balance, the Committee agreed that the ICERs would be unlikely to increase to a point where telaprevir would not be considered cost effective. The Committee concluded that telaprevir in combination with peginterferon alfa and ribavirin represents a cost-effective use of NHS resources.

See Sections 3 and 4 of the original guideline document for details of the economic analysis provided by the manufacturer, the Evidence Review Group comments, and the Appraisal Committee considerations.

Method of Guideline Validation

Description of Method of Guideline Validation

Consultee organisations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated for each recommendation.

The Appraisal Committee considered clinical and cost-effectiveness evidence and a review of this submission by the Evidence Review Group. For clinical effectiveness, two randomised controlled trials (RCTs) were the main source of evidence. For cost-effectiveness, the manufacturer's model was considered.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of telaprevir for the treatment of genotype 1 chronic hepatitis C

Potential Harms

The summary of product characteristics lists the following adverse reactions for telaprevir: anaemia, rash, thrombocytopenia, lymphopenia, pruritus, diarrhoea and nausea.

For full details of adverse reactions and contraindications, see the summary of product characteristics.

Contraindications

Contraindications

For full details of adverse reactions and contraindications, see the summary of product characteristics.

Qualifying Statements

Qualifying Statements

- This guidance represents the views of the National Institute for Health and Clinical Excellence (NICE) and was arrived at after careful
 consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical
 judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate
 to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded
 that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to
 have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with
 compliance with those duties.

Implementation of the Guideline

Description of Implementation Strategy

- The Secretary of State and the Welsh Assembly Minister for Health and Social Services have issued directions to the National Health Service (NHS) in England and Wales on implementing National Institute for Health and Clinical Excellence (NICE) technology appraisal guidance. When a NICE technology appraisal recommends use of a drug or treatment, or other technology, the NHS must usually provide funding and resources for it within 3 months of the guidance being published. If the Department of Health issues a variation to the 3-month funding direction, details will be available on the NICE website. When there is no NICE technology appraisal guidance on a drug, treatment or other technology, decisions on funding should be made locally.
- NICE has developed tools to help organisations put this guidance into practice (listed below). These are available on the NICE website (http://guidance.nice.org.uk/TA252 ______).
 - Costing template and report to estimate the national and local savings and costs associated with implementation
 - Audit support for monitoring local practice

Implementation Tools

Audit Criteria/Indicators

Patient Resources

Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

National Institute for Health and Clinical Excellence (NICE). Telaprevir for the treatment of genotype 1 chronic hepatitis C. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012 Apr. 47 p. (Technology appraisal guidance; no. 252).

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Apr

Guideline Developer(s)

National Institute for Health and Care Excellence (NICE) - National Government Agency [Non-U.S.]

Source(s) of Funding

National Institute for Health and Clinical Excellence (NICE)

Guideline Committee

Appraisal Committee

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

Guideline Status
This is the current release of the guideline.
Guideline Availability Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site
Availability of Companion Documents
The following are available:
 Boceprevir and telaprevir for the treatment of genotype 1 chronic hepatitis C. Costing template. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012. (Technology appraisal guidance; no. 252). Electronic copies: Available from the National Institute for Health and Clinical Excellence (NICE) Web site Telaprevir for the treatment of genotype 1 chronic hepatitis C. Clinical audit tool. London (UK): National Institute for Health and Clinical Excellence (NICE); 2012. (Technology appraisal guidance; no. 252). Electronic copies: Available from the NICE Web site Telaprevir for the treatment of genotype 1 chronic hepatitis C. Evidence Review Group report. Southampton (UK): Southampton Health Technology Assessments Centre; 2011 Dec 20. 74 p. Electronic copies: Available from the NICE Web site
Patient Resources
The following is available:
 Telaprevir for genotype 1 chronic hepatitis C. Understanding NICE guidance. Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence; 2012 Apr. 6 p. (Technology appraisal guidance; no. 252). Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence Web site
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NGC Status

This summary was completed by ECRI Institute on July 18, 2012. This summary was updated by ECRI Institute on April 13, 2012 following the U.S. Food and Drug Administration advisory on Incivek (telaprevir).

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